IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	GIL M. VARDI et al.	Confirmation No.:	3207
Serial No.:	10/762,562	Examiner:	THOMAS SWEET
Filing Date:	JANUARY 23, 2004	Group Art Unit:	3774
Docket No.:	1001.2273105	Customer No.:	28075
Title:	CATHETER WITH ATTACHED FLEXIBLE SIDE SHEATH		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF Assistant Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450	**CERTIFICATE OF ELECTRONIC TRANSMISSION** I hereby certify that this paper is being electronically transmitted to the United States Patent and Trademark Office on the date shown below. Lynn Thompson — October 31, 2008 Lynn Thompson — Date

Applicants have carefully reviewed the Final Office Action dated July 1, 2008. Currently, claims 1-7, 9, and 24 remain pending. Claims 1-7, 9, and 24 stand finally rejected. Applicants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

On page 2 of the Final Office Action, claims 1-7, 9, and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (U.S. Patent No. 6,165,195) in view of Fischell et al. (U.S. Patent No. 5,749,825). After careful review, Applicant must respectfully disagree.

Turning to claim 1, which recites:

> 1. (Previously Presented) A method of positioning a main stent in a main vessel at a vessel bifurcation such that a side opening in the main stent is positioned at an ostium of a branch vessel, the method comprising:
>
> positioning a main guidewire in the main vessel such that a distal end of the main guidewire extends past the vessel bifurcation;
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> advancing a stent delivery system over the main guidewire to a position proximate the bifurcation, the stent delivery system comprising a catheter with a flexible side sheath attached thereto, wherein the catheter is received over the main guidewire, and wherein the main stent is positioned over the catheter with the flexible side sheath positioned to pass through an interior of the main stent and out the side opening in the main stent, the flexible side sheath having a distal end portion extending distal of the side opening of the stent;
>
> subsequently, advancing a branch guidewire through the flexible side sheath attached to the catheter and into the branch vessel;
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> subsequently, advancing the catheter over the main guidewire while

advancing the flexible side sheath over the branch guidewire, wherein the distal end portion of the flexible side sheath advances into the branch vessel; and

viewing relative movement of a marker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel.

Nowhere does Wilson et al. or Fischell et al., either alone or in combination, appear to teach or suggest "viewing relative movement of a maker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel", as recited in claim 1.

In the Final Office Action, the Examiner cites column 17, line 64 through column 18, line 14 of Wilson et al. as teaching placing markers on components for assisting in proper alignment. The cited passage recites:

> In order to assist in properly aligning both proximal angled stent 10 and main-vessel stent 20 in side-branch vessel 5 and main-vessel 6, respectively, positioning guide wire lumen 39A, on side-branch catheter 31, and guide wire lumen 55A, on main-vessel catheter 50, can be radiopaque, or have a radiopaque marker associated therewith so that they are visible under fluoroscopy. Thus, when advancing side-branch catheter 31 and main-vessel catheter 50, the proper orientation can be more easily determined by viewing the position of positioning guide wire lumen 39A in connection with main-vessel 6 or positioning guide wire lumen 55A in connection with aligning aperture 25 with side-branch vessel 5. Additionally, positioning guide wire 56A for positioning main-vessel stent 20 and positioning guide wire 41A for positioning angled stent 10 are either radiopaque or have radiopaque portions, such as gold markers, to assist in positioning and orienting the catheters and stents during implantation and deployment.

(Emphasis added). This passage appears to merely teach providing radiopaque markers on the guidewire lumen 55A of the main-vessel catheter 50, or for a side-branch catheter, providing markers on guidewire lumen 39A. In either case, the passage appears to teach using radiopaque markers on a single lumen of the catheter to determine the proper

orientation and alignment of the catheter with the side-branch vessel 5. Nowhere does this passage or any other passage of Wilson et al. appear to teach or suggest using radiopaque markers in both the main guidewire lumen and the secondary guidewire lumen.

Furthermore, in a configuration with all of the radiopaque markers in the same lumen, as disclosed by Wilson et al., there would be no relative movement between the markers. As such, nothing in Wilson et al. appears to teach or suggest "viewing relative movement of a maker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel", as recited in claim 1. As the Examiner is aware, § 2141 of the MPEP states:

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn,* 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

(Emphasis added). As such, in order to support the legal conclusion of obviousness, the Examiner needs to clearly articulate the reasons why it would be obvious to perform a method step of "viewing relative movement of a maker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel" when the cited references teaches a device in which the markers would never exhibit a change in relative movement. Applicant respectfully asserts that the Examiner has failed to provide such articulated reasons.

Furthermore, nowhere does the combination of Wilson et al. and Fischell et al. appear to teach or suggest "the flexible sheath having a distal end portion extending distal of the side

opening of the stent", as recited in claim 1. In the Final Office Action, the Examiner acknowledges that Wilson et al. fails to teach or suggest this limitation, but then relies on Fischell et al. as teaching such a limitation. Applicant respectfully asserts that modifying the catheter of Wilson et al. to include the flexible side sheath of Fischell et al. would not arrive at the claimed invention.

Fischell et al. appears to teach a sheath having a proximal end that extends only a short distance proximal of the stent. In such a configuration, it does not appear that a branch guidewire could be advanced through the side sheath subsequent to the stent delivery system being advanced through the vessel. In fact, in such a configuration, it appears that the stent delivery system would need to be advanced over the branch guidewire prior to the stent delivery system being advanced through the vessel. Thus, modifying the device of Wilson et al. to include the side sheath of Fischell et al. does not appear to arrive at the claimed invention.

Therefore, for at least these reasons, claim 1 is believed to be patentable over Wilson et al. and Fischell et al. For similar reasons and others, claims 2-6 and 24, which depend from claim 1 and include additional limitations, are believed to be patentable over Wilson et al. in view of Fischell et al.

Turning to claim 7, which recites:

> 7. (Previously Presented) A method of positioning a main stent at a vessel bifurcation between a main vessel and a branch vessel such that a side opening in the main stent is positioned at an ostium of the branch vessel, the method comprising:
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> positioning a main guidewire in the main vessel such that a distal end of the main guidewire extends past the bifurcation;
>
> advancing a stent delivery system over the main guidwire to a position proximate the bifurcation, the stent delivery system comprising a catheter with a flexible side sheath attached thereto, wherein the catheter is received over the main guidewire, and wherein the main stent is positioned over the catheter with the flexible side sheath positioned to pass through the interior of the main stent and out the side opening in the main stent, the flexible side sheath having a distal end portion extending distal of the side opening of the stent;
>
> subsequently, advancing a branch guidewire through the flexible side sheath and into the branch vessel; and
>
> subsequently, advancing the catheter over the main guidewire while advancing the flexible side sheath over the branch guidewire, wherein the distal end portion of the flexible side sheath advances into the branch vessel such that the side opening in the main stent is positioned at the ostium of the

branch vessel.

As discussed previously, nowhere does Wilson et al. or Fischell et al. appear to teach or suggest "the flexible side sheath having a distal end portion extending distal of the side opening of the stent", as recited in claim 7. Therefore, for at least these reasons, claim 1 is believed to be patentable over Wilson et al. and Fischell et al. For similar reasons and others, claim 9, which depends from claim 1 and includes additional limitations, is believed to be patentable over Wilson et al. in view of Fischell et al.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reconsideration and withdrawal of the rejection are respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By their Attorney,

Date: Oct 31, 2008

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